

Electronic Prior Authorization Standard Straw Vote

**What Is Industry's Recommendations
for Prior Authorization Processing?**

**NCPDP ePA Workflow-to-Transactions Task Group
June 14, 2012**

Agenda

3:00 to 3:10 EDT (10 minutes)	Background Information	Tony, Lynne
3:10 to 3:25 EDT (15 minutes)	Statements for NCPDP ePA Transaction	Bruce Wilkinson, CVS Caremark
		Susan Hoo, Caremark Consultant
		Peter Kaufman, MD, DrFirst
		Dan Renner, CoverMyMeds
3:25 to 3:35 EDT (10 minutes)	Questions & Answers on Statements for NCPDP ePA Transaction	Task Group
3:35 to 3:50 EDT (15 minutes)	Statements for X12 278/275	Steve Ellwing, AMA
		John Kelly, AMA Consultant
3:50 to 4:00 EDT (10 minutes)	Questions & Answers on Statements for X12 278/275	Task Group
4:00 to 4:05 EDT (5 minutes)	Rebuttal of NCPDP ePA Transaction	John Kelly
4:05 to 4:10 EDT (5 minutes)	Rebuttal of X12 278/275	Susan Hoo
4:10 to 4:12 EDT (2 minutes)	Voting Instructions	Lynne
4:13 to 4:25 EDT (12 minutes)	Vote	Task Group
4:25 to 4:30 EDT (5 minutes)	Wrap Up	Tony

Electronic Prior Authorization Milestones



Federal government (HIPAA, MMA, CMS/AHRQ) efforts to encourage development and adoption of ePA has brought us to an inflection point. The industry must now take over.

NCPDP ePA Task Group Formed

- Standard transactions mapped
- Gaps identified
- HL7 PA Attachment created (2005)

CMS/AHRQ pushes forward

- Expert Panel formed
- Resolution of which SDO would own ePA
- Exception to HIPPA resolved
- Value model created

Renewed Interest

- More pilots
- Economic value
- State legislation

Aug 1996

Nov 2004

2006

2008

2009

2011

HIPAA passes

- X12 278 named "prior authorization" transaction standard

MMA ePrescribing Pilot Tests

- "Menagerie of ePA standards" pilot tested (X12 278 v5010, 275 v5010, HL7 PA Attachment)
- Recommendation was that there be one standard – not X12 278

New draft Standard Created

- Housed in NCPDP
- Compatible with emerging technology
- No pilot test

Reason for the 2008 Decision by the Expert Panel to Create NCPDP draft Standard



1. Concerns about redundant information being required in multiple standards, and the resulting complexity.
2. Desire to have interoperability with the real-time benefit check, understanding the issues associated with the current formulary paradigm, which leads to plan- or group-level formulary and benefit (and ePA false positives).
3. Apprehension about time-to-market of the X12 278, in particular, and the HL7 PA attachment, as well. The 278 is constrained by HIPAA, where legislation must be passed in order to use a newer version of a standard.
4. Aspirations for completeness and utility. Pilot modifications would be in the 6010.
5. Concerns for software vendors and implementers. It was observed that, in order to implement the model tested in the 2006 pilots – the X12 278 and 275, HL7 PA Attachment, NCPDP F&B and NCPDP SCRIPT, vendors/implementers would have to be involved in three standard development organizations.
6. It was also observed that X12 is largely a SDO focused on payer administrative and financial transactions. Expert Panel was concerned that ePA had a clinical element to it that could best be understood by clinicians such as pharmacists within NCPDP.

Things to Think About

- The industry is looking for us to solve this problem. We represent “the industry.” We have to make a decision, and that’s what today is about.
- In 2008, CMS’s OEES gave us the OK to create a new standard, indicating that they supported whatever the industry felt was the right thing to do.
 - I believe HIPAA was/is a policy lever, not a directive
 - Leaders of OEES have changed
 - OEES’s support does not constitute a HIPAA exception, which we would still have to get
- This decision is like anything: there is no clear-cut right answer. There are pros/cons to each position.
- Right or wrong, in 2009, we (the industry) made a decision. As a result of this, decisions have been made, substantial work has been done, monies have been invested.

Ground Rules

- We have a very tight agenda, and we're going to have to stick to it. Again, the industry needs to make a decision, and my goal is to come out of here with a direction for the task group.
- Everyone needs to keep their phones on mute unless you're commenting.
- If you're not presenting, you will have the opportunity to ask questions. When you have that opportunity, we respectfully ask that you truly ask a question, not state your opinion. There will be a time for rebuttal.
- Treat everyone with respect.

Procedures

- We will stick closely to the agenda.
- Two options are being represented:
 - NCPDP ePA standard transactions + attachment when necessary OR
 - X12 278 + X12 275 + attachment when necessary
- One or more people will be given an opportunity to advocate for each position.
- The Task Group will be given the opportunity to ask questions.
- Each side will be given the opportunity to rebut.
- We will take a straw vote. Any Task Group member on this call will be allowed one vote.
- One thing we won't be able to do that we do in Work Group meetings is "friendly amendments" or clarifications. You each get one vote and for one of two options.
- We will decide next steps after tallying the vote and on the next Task Group call.

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Current Factors

- Based on pilots, Formulary and Benefit Standard was enhanced to include the ability to send PA questions, as well as drug, answer, and applicability lists. Process begun to update to version 3.0 in the MMA regulations. Transition period for industry with the recommended compliance date of July 1, 2014 for NCPDP Formulary and Benefit Standard Version 3.0.
- For the pilot, LOINC values were created to help standardize the questions, rather than reading free text.
- X12 and NCPDP support frequent update cycles to standards in response to industry requests. (Factor: industry timeframe to adoption.)
- Any recommendations will require standards development work if business needs not met.
- Any recommendations might require a waiver for pilot testing if a standard version is already named in HIPAA.
- Consideration for Meaningful Use and other regulatory requirements is important for future planning.

Current Factors

- X12 278/275 Technical Report 3 – version 6020 informational forum held June 4-6, 2012
 - X12 incorporated findings from MMA 2006 ePrescribing pilots into X12 278 v6020
- Attachments - NCVHS heard testimony from the industry and recommended the following to Sec HHS. <http://www.ncvhs.hhs.gov/120302lt1.pdf> The Sec HHS doesn't have to accept the recommendations; mostly they do.
 - Section 1104 of ACA directs the Secretary to publish final regulations adopting national standards, implementation specifications and operating rules for health care claim attachments by no later than January 1, 2014, with a compliance date of no later than January 1, 2016.
 - Unclear how far the 'attachment' definition will reach.
- *The next slides attempt to outline the options, but there may be corrections that need to be made. While drug PA is cited, it is only to focus this task group's expertise, but all PA should be kept in mind.*

Are these the electronic functions needed?

- The prescriber system to obtain information if a **PA is needed** for a patient for a medication.
- The prescriber system to obtain what it takes to fulfill a drug **PA (forms/questions/answers/clinical info/etc)**.
- The prescriber system to send what is needed to fulfill a drug **PA “simple responses”** or requires more complex clinical response.

Electronic Attachments

- An attachment *might* function as the mechanism
 - to exchange the criteria needed to fulfill a drug PA (the questions, what is needed for consideration in a drug PA),
AND/OR
 - a mechanism to exchange the clinical information in fulfillment of a drug PA (the clinical response from the prescribing system to obtain a drug PA).
- An attachment *might* contain
 - an unstructured document (PDF, image, etc)
OR
 - a series of questions and answer choices for the criteria needed to fulfill a drug PA
OR
 - the clinical document sections necessary to fulfill a PA. Example, a CDA template defined by the industry that contains the sections in the CDA that are thought to be of use in PA (allergy, lab, history, etc). The payer pulls from the CDA sections for the PA “answers” .
- HL7 has an implementation guide for the PA Attachments but it was never balloted; attachments are now based on the clinical document architecture.

PA is needed?

- The prescriber system to obtain information if a **PA is needed** for a patient for a medication.
 - The system can obtain this information via:
 - Formulary and Benefit 3.0 for benefits/coverage/PA drugs/PA questions with answer choices from the payers, *with*
 - 270/271 to obtain patient's eligibility information and Formulary and Benefit identifiers
 - *Is the 271 able to say if PA is needed based on the patient and drug that is sent on the 270?*
- OR
- Draft Real-time Benefit Check

- Note: it is recognized that use of the F&B solution may not provide specific PA information at a **patient level**. The 270/271 may assist in this, or that the F&B has provided enough information is enough for the prescribing system to check for PA fulfillment information (next slide).

What does it take to fulfill a drug PA?

- The prescriber system to obtain what it takes to fulfill a drug PA (forms/questions/answers/clinical info/etc).

- The system can obtain what it takes to fulfill a drug PA via:

- Send a 278 to request information, receive a 278 from payer with link to where PA forms can be found

OR

- Send a 278 to request information, receive a 278 from payer with questions

- *Note, no answer choice at this time. Questions via free text?*

OR

- Send a 278 to request information, receive a 278/275/Attachment from payer with questions and answer choices

- *Note, attachment could be a PDF, image, etc, or HL7 CDA*
 - *Possible suggestion to include the PAQuestionSet pertinent pieces as a “standardized” attachment.*

OR

- Send a draft PAQuestionSetRequest, receive a draft PAQuestionSetResponse, supports an attachment
 - *Note, attachment could be a PDF, image, etc, or HL7 CDA*

Send what is needed to obtain drug PA

- The prescriber system to **send what is needed to fulfill a drug PA (“simple responses”)**.
 - The system can send the fulfillment information via:
 - 278 to the payer with information to follow via non-transaction means (mail/fax/etc)
- OR
 - 278/275/Attachment to the payer with completed questions
 - *Note, attachment in this instance is a unstructured document (PDF, image, etc)*
 - *Answers in the unstructured document*
- OR
 - draft PARrequest to the payer with completed questions
 - *Note, attachment could be a PDF, image, etc, or HL7 CDA*
- The payer responds to fulfillment request.

Send what is needed to obtain drug PA (more complex clinical information)

- The prescriber system to send **what is needed to fulfill a drug PA (requires more complex clinical response)**.
 - The system can send the fulfillment information via:
 - 278 to the payer with clinical information to follow via non-transaction means (mail/fax/etc)
- OR
 - 278/275/CDA to the payer with completed questions with clinical information
 - *Note, attachment in this instance is a structured document*
- OR
 - draft PARrequest to the payer with completed questions with CDA containing clinical information
- The payer responds to fulfillment request.

Minnesota Uniform Form for Prescription Drug Prior Authorization (PA) Requests and Formulary Exceptions

INSTRUCTIONS

Important: Please read all instructions and information before completing the form.

Please do NOT send this form to a patient's employer or to the Minnesota Department of Health (MDH) or to the Minnesota Administrative Uniformity Committee (AUC).

Note: This version of the form (C-1.0) is current as of July 2010, and supersedes the following previous versions of Minnesota Department of Health forms for PA requests and formulary exceptions:

- Example Minnesota Prescription Drug Prior Authorization (PA) Request Form, version 1.0 2/15/10
- Minnesota Uniform Formulary Exception Form, version 1.0 September, 2009

This form will not change frequently. The form version number and most recent revision date are displayed in the lower right corner.

Overview:

The following form is made available by the Minnesota Department of Health (MDH) pursuant to statute, to facilitate exchanges of information between prescribers and patients' insurance carriers, HMOs, Pharmacy Benefits Managers (PBMs), or other payers* of prescription drug claims.

Intended use and requirements:

The form is intended primarily for use by prescribers, or those designated and authorized to act on behalf of prescribers, to:

1. Request an exception to a prescription drug formulary.

- Requests for formulary exceptions are requests to make nonformulary prescription drugs available to a patient as a formulary drug.
- Laws 2010, chapter 336, section 4 requires that all health care providers must submit requests for formulary exceptions using the uniform form, and that all payers must accept this form from health care providers. No later than January 1, 2011, the uniform formulary exception form must be accessible and submitted by health care providers, and accepted and processed by group purchasers, through secure electronic transmissions. Note: A previous restriction in law that facsimile was not considered "secure electronic transmission" was removed in 2010.

2. Request a prior authorization (PA) for a prescription drug.

- Prescription drug prior authorization requests are requests for pre-approval from a payer for specified medications or quantities of medications.
- Laws 2010, chapter 336, section 5 requires that by January 1, 2015, drug PA requests must be accessible and submitted by health care providers, and accepted by payers, electronically through secure electronic transmissions.

Additional Instructions:

- Prescribers, or their designees, use parts A-F as applicable. Payers making the form available on their websites may pre-populate section A. Payers use section G when responding to requests.
- Payers may request additional information or clarification needed to process formulary exceptions and PA requests.
- Payers may supply additional instructions or other relevant or legally required information with their response.
- Complete section F when submitting prescription drug PA requests to the Minnesota Department of Human Services.

* Note: The term "payers" is used to avoid possible confusion. The electronic submission and acceptance requirements of Minnesota Statutes § 62J.497, subd. 4 and 5, apply to "group purchasers". The term "group purchaser" is defined in Minnesota Statutes § 62J.03, subd. 6 and can be considered more commonly as "payer".



Minnesota Uniform Form for Prescription Drug Prior Authorization (PA) Requests and Formulary Exceptions

Please do NOT send this form to a patient's employer or to the Minnesota Department of Health (MDH) or to the Minnesota Administrative Uniformity Committee (AUC).

See additional instructions and overview, Instructions page.

Please check the appropriate box below (check only one box). This form is being used for:

☐ Formulary Exception ☐ Prior Authorization (PA) Request ☐ Unsure/Unknown

A Destination This form is being submitted to: (Payers making this form available on their websites may pre-populate section A.)

Payer Name: _____

Payer Contact Name: _____
(IF AVAILABLE)

Payer Address: _____ City, State, ZIP: _____

Payer Phone: _____ Secure Fax: _____ Other: _____

B Patient Information

When filling Patient Health Plan ID number below, please note: If the patient has prescription benefits that are separate or "carved out" from the health plan benefits, provide the patient's prescription benefit card ID number (the "cardholder ID"). If the patient's prescription benefits are integrated with the health plan coverage (if there is no separate prescription benefit ID number), provide the patient's health plan ID number.

Patient Name: _____ DOB: _____
(LAST, FIRST, MI) (MM / DD / YYYY)

Patient Address: _____ City, State, ZIP: _____

Gender. Please Check Box: ☐ Male ☐ Female ☐ Unknown

Health Plan or Prescription Plan: _____ Patient Health Plan ID No.: _____
(OR PRESCRIPTION PLAN ID IF DIFFERENT THAN HEALTH PLAN ID)

C Prescriber Information

Prescriber Name: _____ NPI: _____ Specialty: _____
(LAST, FIRST, MI)

Prescriber Business Address: _____ City, State, Zip: _____

Prescriber Phone: _____ Prescriber Secure Fax: _____

Prescriber Point of Contact (POC) Name: _____ POC Phone: _____ POC Secure Fax: _____
(IF DIFFERENT THAN PRESCRIBER) (IF DIFFERENT THAN PRESCRIBER)

Clinic/Location/Facility Name: _____ Clinic/Location/Facility Contact Name: _____

Clinic/Location/Facility Phone: _____ Secure Clinic/Location/Facility Fax: _____

Clinic/Location/Facility Address: _____ City, State, ZIP: _____

D Prescription Drug Information (Medication information)

When completing this section and the following section (E), medication "strength" is usually expressed in milligrams, e.g., 30 mg, 15 mg/ml, etc. Medication "dosing schedule" is used to report how often the patient will take/use the medication, e.g., daily, four times per day, every four hours, as needed, etc.

Drug Being Requested: _____ Strength: _____
(REQUESTED DRUG NAME) (E.G., 30 MG, 15 MG/ML, ETC)

Dosing Schedule: _____ Date Therapy Initiated: _____

Duration of Therapy Expected: _____ Authorization Start Date: _____

Clinical Drug Trial Request? ☐ Yes ☐ No Is Dispense as Written (DAW) Specified? ☐ Yes ☐ No

(NOTE: THE MINNESOTA DEPT. OF HUMAN SERVICES DOES NOT COVER CLINICAL DRUG TRIALS.)

Rationale for DAW? _____

Is patient currently being treated with the drug requested? ☐ Yes ☐ No Date Started: _____

Minnesota Uniform Form for Prescription Drug Prior Authorization (PA) Requests and Formulary Exceptions

E Patient Clinical Information

Diagnosis Related to Medication Request: _____

(INCLUDE ICD-9 CODES WHEN AVAILABLE)

Drug Allergies: _____

(IF RELEVANT TO THIS REQUEST)

Height: _____

(IF RELEVANT TO THIS REQUEST)

Weight: _____

(IF RELEVANT TO THIS REQUEST)

PREVIOUS THERAPIES TRIED / FAILED (list name, date prescribed, etc., in boxes below. Note: Medication "strength" is usually expressed in milligrams, e.g., 30 mg, 15 mg/ml, etc. Medication "dosing schedule" is used to report how often the patient will take/use the medication, e.g., daily, four times per day, every four hours, as needed, etc.):

Drug Name	Strength	Dosing Schedule	Date Prescribed	Date Stopped	Describe Adverse Reaction or Efficacy Failure
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

RATIONALE FOR REQUEST (and also include any additional pertinent clinical information/comments regarding rationale): _____

F Pharmacy Information – For PA Requests to the Minnesota Department of Human Services (DHS)

Pharmacy Name: _____ National Provider Identifier: _____ Pharmacy Phone: _____

Pharmacy Address: _____ City, State, Zip: _____

NDC Number for Prescription Drug Being Requested: _____ Pharmacy Fax: _____

G Request Determination (may be completed by payers and sent to providers)

Date Request Received by Payer: _____ Date of Decision: _____

Payer Responder/Contact Name: _____ Payer Respondent/Contact Phone and/or Email: _____

Request Approved/Denied: ☒ Approved ☐ Denied

Pharmacy Authorization/Reference No.: _____
(IF APPLICABLE TO PAYER)

Comments Regarding Decision: _____
(INCLUDE EFFECTIVE AND END DATES OF DECISION IF APPLICABLE)

Additional Information or Instructions

Note: Group purchasers may supply additional instructions or other relevant or legally required information with their response. Examples of additional information might include: Appeals rights and processes; other notifications; other information required for legal or clarification purposes. _____

CONFIDENTIALITY NOTICE: The information in this form is confidential and intended for the use of the recipient. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or taking of any action in reliance of the contents of this communication is strictly prohibited. If you have received this form in error please immediately notify the sender to arrange for its return. Thank you for your assistance.





**Maryland Pharmacy Program - Preferred Drug Program
Medication Change Fax Form**

AUTHORIZED PRESCRIBER:

(Physician, dentist, PA, nurse practitioner, podiatrist)

RECIPIENT:

Name: _____
First Last

Name: _____
First Last

Date of Birth: ____/____/____

The above beneficiary has a prescription order from you for the following State of Maryland non-preferred medication.

Current Non-Preferred or Tier 2 Medication Order

Drug Name	Strength	Form	Quantity
Sig: _____			Refills remaining: _____

Please review this order and notify this pharmacy if a change can be made to a Preferred or a Tier 1 medication.

Pharmacy Name: _____

Pharmacy Telephone: (____) - ____ - ____

Pharmacy Fax: (____) - ____ - ____

Complete Preferred Drug List available at www.providersynergies.com/services/documents/MDM_PDL.pdf

Preferred or Tier 1 Medication: I authorize change to the following Preferred or Tier 1 medication.

Drug Name	Strength	Form	Quantity

Authorized Prescriber Signature: _____

DEA # _____ Telephone (____) - ____ - ____

Date: _____

Form revised 02/01/2008



Tier 2 and Non-Preferred Antipsychotic Prior Authorization Form

Prescriber Information

Prescriber Name: _____ NPI #: _____ Specialty: _____

Mailing Address: _____

Tel: _____ Fax: _____ Email: _____

Patient Information

Patient Name: _____ Patient MA#: _____

Mailing Address: _____

DOB (MM/DD/YY): _____ Male _____ Female _____ Height (inches): _____ Weight (pounds): _____

DSM - IV - TR Diagnosis (check all that apply)

- | | | |
|--|---|---|
| <input type="checkbox"/> ADHD | <input type="checkbox"/> Generalized Anxiety Disorder | <input type="checkbox"/> PTSD |
| <input type="checkbox"/> Anti-social or Borderline Personality D/O | <input type="checkbox"/> Major Depressive Disorder | <input type="checkbox"/> Schizoaffective D/O |
| <input type="checkbox"/> Asperger's Disorder or PDDNOS | <input type="checkbox"/> Mental Retardation | <input type="checkbox"/> Schizophrenia |
| <input type="checkbox"/> Autistic Disorder | <input type="checkbox"/> Obsessive Compulsive D/O | <input type="checkbox"/> Social Phobia |
| <input type="checkbox"/> Bipolar Disorder | <input type="checkbox"/> Panic Disorder | <input type="checkbox"/> Tourette's Disorder |
| <input type="checkbox"/> Conduct or Oppositional Defiant D/O | <input type="checkbox"/> Psychotic D/O Not Schizophrenia (specify): _____ | <input type="checkbox"/> Other (specify): _____ |
| <input type="checkbox"/> Dementia | | |

Target Symptoms (check all target symptoms for which drug is being prescribed)

- | | | |
|-------------------------------------|---|--|
| <input type="checkbox"/> Aggression | <input type="checkbox"/> Hallucinations | <input type="checkbox"/> Mania |
| <input type="checkbox"/> Assault | <input type="checkbox"/> Insomnia | <input type="checkbox"/> Mood lability |
| <input type="checkbox"/> Delusion | <input type="checkbox"/> Irritability | <input type="checkbox"/> Self-injurious Behavior |
| <input type="checkbox"/> Depression | | <input type="checkbox"/> Other: _____ |

Antipsychotic for which authorization is being sought: (check)

- | | | |
|-----------------------------------|--|--|
| <input type="checkbox"/> Abilify® | <input type="checkbox"/> Invega Sustenna® | <input type="checkbox"/> Saphris® |
| <input type="checkbox"/> Fanapt® | <input type="checkbox"/> Latuda® | <input type="checkbox"/> Seroquel XR® |
| <input type="checkbox"/> Fazaclo® | <input type="checkbox"/> olanzapine | <input type="checkbox"/> Zyprexa Relprevv® |
| <input type="checkbox"/> Invega® | <input type="checkbox"/> olanzapine/fluoxetine | <input type="checkbox"/> other: _____ |

Dosage Form: _____ Strength: _____ Frequency: _____ Quantity: _____

Dosage Form: _____ Strength: _____ Frequency: _____ Quantity: _____

Is requested medication a continuation of therapy from an inpatient setting? ☐ Yes ☐ No

Does the patient have a condition that prevents the use of the preferred medication? ☐ Yes ☐ No

If yes, please specify: _____

Is there a drug-drug interaction between another medication and the preferred medication? ☐ Yes ☐ No

If yes, please specify: _____

Has the patient experienced treatment failure with other medications? ☐ Yes ☐ No

If yes, please list which medications the patient has tried:

Medication Name	Strength/Frequency	Duration of Treatment	Compliance (at least 6 days/wk)	Reason for Discontinuation

I certify that the benefits of antipsychotic treatment for this patient outweigh the risks.

Prescriber Signature: _____ Date: _____
(DHMH Sept. 2012)



**Maryland Pharmacy Program
Request for Rx Prior Authorization
Preferred Drug Program**

[illegible][illegible][illegible][illegible]

Person Completing Form _____

[illegible]

Check if generic is not acceptable ☐ (Prescriber must complete DHMH Medwatch Form)

Strength	Dosage Form	Quantity	Directions
----------	-------------	----------	------------

1. Diagnosis for use of this medication? _____

2. Why have you chosen to use a drug that is not a preferred drug nor a recommended Tier 1 drug?

☐ Inadequate response to alternatives ☐ Allergy to alternates ☐ Adverse event with alternatives ☐ Select all

☐ Other (describe) _____ that apply

The Preferred Drug List allows the State to provide recipients quality drugs that are safe and cost-effective. Current list of non-preferred drugs requiring PA is available at http://providersynergies.com/services/documents/MDM_PDL.pdf

Signature of Prescriber_____

FAX TO: Maryland Pharmacy Program

Fax: (866) 440 - 9345

PA HELPDESK: (800)932-3918

37663



